

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	MDL No. 2419 Master Dkt. 1:13-md-02419-RWZ
THIS DOCUMENT RELATES TO: All Tennessee Actions.	Judge Rya Zobel

**PLAINTIFFS’ STEERING COMMITTEE’S RESPONSE TO THE TENNESSEE
CLINIC DEFENDANTS’ OPPOSITION TO THE MASSACHUSETTS BOARD OF
PHARMACY’S MOTION FOR PROTECTIVE ORDER**

I. Introduction

The Plaintiffs’ Steering Committee (the “PSC”) now files this Response to the Tennessee Clinic Defendants’ Opposition¹ (“Opposition”) to the Massachusetts Board of Pharmacy’s (the “Board”) Motion for Protective Order.² The Tennessee Clinic Defendants served a third-party subpoena³ on the Board demanding that the Board produce documents and sit for a 30(b)(6) deposition. Now, through their Opposition, the Tennessee Clinic Defendants seek to compel the Board to comply with the subpoena.⁴

The Board states in its pleading that it will produce responsive documents and, like the U.S. Food and Drug Administration (the “FDA”),⁵ seeks a Protective Order to prohibit the 30(b)(6) deposition.⁶ The PSC maintains that, given the Tennessee Clinic Defendants’ proffered

¹ Dkt. No. 2029.

² Dkt. Nos. 1975 and 1976.

³ Dkt. No. 1735.

⁴ Dkt. No. 2029.

⁵ Dkt. No. 1838.

⁶ Dkt. No. 1976.

reasons for needing discovery, the documents the Board has agreed to produce are sufficient, rendering a full 30(b)(6) deposition improper and unnecessary.

II. Tennessee Clinic Defendants Fail to Present any Meritorious Argument Warranting a Deposition of the Board

A. Tennessee Clinic Defendants Are Not Entitled to a Deposition Under Massachusetts or Tennessee Law

As a threshold matter, the Tennessee Clinic Defendants' claim that they are entitled to discovery and 30(b)(6) deposition testimony to attribute fault to the Board is untenable. Despite the Tennessee Clinic Defendants' assertions, it has not been established that Tennessee law will apply on the issues of comparative fault and joint and several liability. As the PSC fully briefed in its submission to this Court, the PSC believes that Massachusetts law applies to the issues of joint and several liability and comparative fault, which prohibits a defendant from attributing fault to a non-party, like the Board and the FDA.⁷ As the Court stated during the Status Conference held on June 24, 2015, presently, the choice of law issue is still pending.

If it is determined that Tennessee law on comparative fault does apply to the issues of comparative fault and joint and several liability, the Tennessee Clinic Defendants cannot rely on such a defense to justify their burdensome discovery requests. Under Tennessee law, establishing a legal duty is an essential element of establishing fault.⁸ Fault cannot be established when no individual duty exists.⁹ And here, fault cannot be attributed to the Board and/or the FDA because those governmental entities did not owe an individual duty to any particular plaintiff.¹⁰

Tennessee courts follow a legal doctrine known as the public duty doctrine.¹¹ Under that legal principal, duties owed by public employees and agencies are owed to the general public,

⁷ Dkt. No. 2004

⁸ *Eaton v. McLain*, 891 S.W.2d 587 (1994).

⁹ *Id.*

¹⁰ *Wells v. Hamblen Cnty.*, No. E2004-01968-COA-R3CV, 2005 WL 20017197, 3 (Tenn. Ct. App. Aug. 22, 2005).

¹¹ *Ezell v. Cockrell*, 902 S.W.2d 394 (1995).

not to specific individuals.¹² Under the public duty doctrine, a duty owed to everyone is a duty owed to no one as far as tort liability is concerned.¹³ The Tennessee Court of Appeals explains the public duty doctrine as follows:

The public duty doctrine is a creature of common law, and its purpose is to shield a public employee from “suits for injuries that are caused by the public employee’s breach of a duty owed to the public at large.” 6 *Ezell*, 902 S.W.2d at 397. It is sometimes explained by stating that a duty owed to everyone is a duty owed to no one. *See Brown*, 126 S.W.3d at 43.

As in any other negligence action, a plaintiff must establish the existence of a duty or standard of care in an action for negligence of a government employee. *Ezell*, 902 S.W.2d at 397, 400. In Tennessee, it has long been held that a plaintiff must show the existence of a duty particular to him or her, as distinct from a duty owed to the public in general.¹⁴

Even assuming that Tennessee law will apply to the issues of comparative fault and joint and several liability, fault cannot be attributed either to the FDA or the Board. Any duties owed by those agencies are owed to the general public, not to any particular plaintiff. Because fault cannot be attributed to those governmental agencies at trial, such discovery is improper, irrelevant and unnecessary.

B. Even if this Court Rules Evidence of Fault May be Discovered from the Board, a Deposition Remains Improper, Burdensome and Unnecessary

The Tennessee Clinic Defendants present three other reasons why they need a full 30(b)(6) deposition, all of which are satisfied by the Board’s production of documents and/or documents that are already available to the Tennessee Clinic Defendants.

First, the Tennessee Clinic Defendants claim they need testimony from the Board to rebut the plaintiffs’ allegations that the Clinic Defendants failed to comply with the applicable

¹² *Id.*

¹³ *Brown v. Hamilton County*, 126 S.W.3d 43 (2003).

¹⁴ *Wells v. Hamblen County*, 2005 WL 2007197.

standard of care by failing to obtain information about NECC from the Board and failing to visit NECC's facility prior to purchasing from them. With regards to failing to obtain information from the Board, the Tennessee Clinic Defendants note that the relevant information they would need is "*when and what* information the Board would have disclosed" had they requested information about NECC.¹⁵ The Tennessee Clinic Defendants can discover what information the Board had available to it at the time the Tennessee Clinic Defendants should have but failed to make inquiries about NECC from the documents the Board will produce. A deposition is not necessary to answer this question.

To rebut the plaintiffs' allegation that the Tennessee Clinic Defendants negligently failed to audit NECC's facility, the Tennessee Clinic Defendants claim they need deposition testimony to know what the Board's visit to NECC in May 2011 would have shown. The relevance of the Board's inspection is questionable as the inspection was made over a year before the first lot of contaminated MPA being compounded. Also, the Tennessee Clinic Defendants are aware that the Board inspected NECC's facility in May of 2011 as the Board publicly released the report of the inspection. Not only does the report detail what the Board saw during the inspection, including the actual pictures taken, it is readily available to the public.¹⁶ Clearly, deposition testimony is not necessary on this issue.

Second, the Tennessee Clinic Defendants also claim they need a full 30(b)(6) deposition to clarify whether NECC was categorized by the Board and the FDA as a "manufacturer" or a "compounder." However, no such ambiguity is shown through the documents cited in the Opposition. The cited text from the 2002 joint inspection of NECC conducted by the Board and the FDA only contains findings from the inspection, not any determination of the categorization

¹⁵ Dkt. No. 2029 at 7.

¹⁶ <http://www.mass.gov/eohhs/docs/dph/quality/boards/necc/03-new-england-compounding-pharmacy-incnew-england-coumpounding-center-inspection-report.pdf>. (Attached as "Exhibit A.")

of NECC.¹⁷ Also, in the FDA memorandum cited by the Tennessee Clinic Defendants, the FDA explicitly states that NECC is categorized as a compounder.¹⁸ In any event, the determination is only relevant, if at all, to the fault of the FDA and/or the Board and, as discussed *supra* at 2-3, such discovery is unnecessary and irrelevant.

Third, the Tennessee Clinic Defendants claim they need a deposition to support claims of comparative fault of other parties.¹⁹ The only other parties the Tennessee Clinic Defendants assert the Board has relevant information about are NECC and the FDA. NECC's fault is discoverable through thousands of pages of documents already made available and, as discussed *supra* at 2-3, the Tennessee Clinic Defendants may not attribute fault to the FDA.

Lastly, the Tennessee Clinic Defendants claim that the PSC put the Board's regulatory authority at issue. This is a mischaracterization of the plaintiffs' allegations. The PSC's deposition questions related to the Tennessee Clinic Defendants' awareness of the Board's limited resources, not the Board's authority.²⁰ The Tennessee Clinic Defendants' bare assertion that the "Board's regulatory authority" is at issue is insufficient to warrant a full 30(b)(6) deposition.²¹

The PSC has confined this response to issues presented in the Opposition that relate to

¹⁷ See Summary of 2002 Joint inspection of NECC conducted by the Board and the FDA (Attached as "Exhibit B").

¹⁸ See FDA Memorandum, February 24, 2003 ("A discussion was held to decide if NECC should be considered a manufacturer or a compounder. *It was decided that current findings supported a compounding role.*")(emphasis added) (Attached as "Exhibit C").

¹⁹ Dkt. No. 2029 at 8.

²⁰ See Deposition of Michael Cotugno, p. 159-60 ("And although a compounding pharmacy may have been regulated by a state board of pharmacy, for instance here NECC by the Mass. Board of Pharmacy, you also were aware back in the 2008 timeframe, in that timeframe, that they had – the Mass. Board of Pharmacy had limited resources to do inspections and audits of compounding pharmacies. Correct?"; "Weren't you aware that their budget was something like between \$100,000 and \$200,000 a year for the entire board of pharmacy in Massachusetts?"); see Deposition of Francis McAteer, p. 233-34 (asking same questions).

²¹ Dkt. No. 2029

the plaintiffs' allegations and briefs filed by the PSC that are still pending.²² The PSC takes no position on the other issues raised in the Opposition.

III. Conclusion

For the reasons set forth herein, the Board's motion for a protective order should be allowed.

Date: July 16, 2015

Respectfully Submitted,

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²² Dkt. No. 2004

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CERTIFICATE OF SERVICE

I, Kimberly A. Dougherty, hereby certify that I caused a copy of the above *Response to the Tennessee Clinic Defendants' Opposition to the Massachusetts Board of Pharmacy's Motion for Protective Order* to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: July 16, 2015

/s/ Kimberly A. Dougherty
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